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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,657	09/18/2001	Richard E. Wooley	UGRF123796	1163

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CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC  
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SEATTLE, WA 98101-2347

EXAMINER
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YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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07/08/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/955,657	<b>Applicant(s)</b> WOOLEY ET AL.	
	<b>Examiner</b> MICAH-PAUL YOUNG	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-15,18-22 and 56-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-15,18-22 and 56-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

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### DETAILED ACTION

**Acknowledgment of Papers Received:** Response dated 12/22/08.

#### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 5-15, 18-22 and 56-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Fischetti et al (USPN 6,423,299 hereafter '299) in view of Farca et al, (*Potentiation of antibiotic activity by EDTA-Tromethamine against three clinically isolated Gram-Positive resistant bacteria, an in vitro investigation*, Veterinary Research Communications, **18**, 1994, pp 1-6) and Viegas et al (USPN 5,958,443 hereafter '443).

The '299 patent disclose a method of inhibiting the proliferation of bacterial infections in various locations including burns and oral mucosa (abstract, claims, col. 8, lin. 12-35), wherein a composition comprising a chelating agent and an active antibacterial formulation is applied to the injury (claims, examples, col. 9, lin. 62-col. 10, lin. 5). Injuries include burns to the skin (col.

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12, lin. 9-14). The chelating agent includes ETDA (claims 5) and the antibacterial agents include neomycin erythromycin, minocycline, tetracycline, and others in a concentration from 0.5-10% (col. 9, lin. 19-28). The chelating agents are included in such a way as to synergistically enhance the other components in the formulation (col. 11, lin. 30-32). The formulation comprises phosphate buffers that regulate the pH of the formulation from 5.5-7.5 (col. 7, lin. 55-60). The bacterial infections that are treated with the formulation include both Gram negative and positive bacterium such as *Pseudomonas* and *Staphylococcus* (col. 3, lin. 43-47, col. 4, lin. 15-20). The formulation includes carriers such as gel-forming polymers and thickening agents (col. 8, lin. 41-col. 9, lin. 12). The reference is silent to the specific synergistic relationship between the chelator, buffer and antibiotic compounds; this relationship is well established as seen in the Farca study.

The Farca study investigated the relationship between EDTA-tromethamine complexes and various well known antibiotic compounds (abstract). The antibiotic compounds include ampicillin, cephalexin, and oxytetracycline (page 3). Formulations were formed using solutions comprising up to 250 mMol/L of EDTA and up to 5mMol/L of tromethamine (page 2). The minimum inhibitory concentrations were determined for each composition based on the specific bacterial strain, and the results were tabulated. It was found that a synergistic relationship was found for ampicillin and especially oxytetracycline against Gram Positive bacteria such as *Staphylococcus aureus*, *hominis* and *Streptococcus faecium*. (page 2). It would have been obvious to apply the concentrations of the Farca study to the formulation of the '299 patent in order improve the synergistic bacterial fighting properties of the chelator/buffer/antibiotic combination.

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The '443 patent discloses a topical wound healing composition comprising chelators such as EDTA (col. 11, lin. 18-20), antimicrobial agents such as tetracycline and amikacin (col. 10, lin. 20-22), along with buffers such as phosphate and tromethamine (TRIS) which maintain the pH of the formulation at 7.4 (col. 11, lin. 35-55). The drugs are present in a concentration from 0.1-60% (col. 11, lin. 28-31), while the buffer is present in a concentration of as much as 5%, which is sufficient to maintain the pH at 7.4 (col. 11, lin. 50-60). The formulation can be applied to wounds as a second skin that delivers active agents to the affected site (col. 5, lin. 1-5). It would have been obvious to include the buffer agents of the '446 patent into the formulation of the '299 patent since they both describe topical wound healing formulation comprising similar chelators, antimicrobial agents and buffering agents.

Regarding the specific concentration of the chelator compounds it is the position of the Examiner that such limitation in view of the prior art are obviated since the general conditions of the claims have been met by the prior art. It is the position of the Examiner that the concentration of chelators is merely an optimizable limitation as long as synergy is maintained. In each embodiment of the '299 patent synergy is maintained. Applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not

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patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

Regarding the claims limitation reciting the identification of a bacterial infection, determining the MIC and concentrations of the chelators and antibacterial agents, it is the position of the Examiner that such limitation are inherent to any treatment method and would be obvious to any artisan of ordinary skill. These steps are basic treatment steps and would be encompassed in the routine practice of the invention of the '299 and '433 patents. These steps are merely a recitation of inherent procedures practiced by every artisan of ordinary skill in the field of bacterial infections and do not impart patentability to the claims.

With these things in mind it would have been obvious to follow the suggestions and teachings of the prior art in order to provide an improved method of treating bacterial infections. The artisan of ordinary skill would have been motivated to combine the chelating concentration of the '979 patent into the treatment method of the '299 in order to maintain the synergistic properties of the components and improve the treatment of the infection. One of ordinary skill in the art upon combining these teachings, suggestions and disclosures would have expected a treatment method suitable for the disinfecting surface injuries.

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

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*Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1,2,5-11 and 56-62 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 14, 15, 18-21, 26-29, 43 and 44 of copending Application No. 10/739,841. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of treating a wound with a composition comprising chelators and antibacterial agents. The claims recite the same chelators and antibacterial agents. Although the claims of the instant invention include further components, the claims of the '657 patent are open to further components that do not change the material properties of the invention. For these reasons the claims of the instant claims would act as obviating art over the '657 claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 1,2,5-11 and 56-62 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 9-19, 23, 24 and 28-43 of copending Application No. 10/812,668. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a wound

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chelating compositions comprising chelators, antibacterial and anti-inflammatory agents. The chelating agents are the same along with similar if not identical active agents. The claims also recite methods of application and kits comprising the formulation and methods of application. The claims of the copending application describe the formulation as a cleanser while the compositions of the instant claims are recited as a wound management composition. However the components of each composition are the same and perform the same function within the art. If issued the instant claims would act as obviating art over the '668 patents and vice versa.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1, 2, 5-15, 18-22 and 56-62 have been considered but are moot in view of the new ground(s) of rejection. However the '299 patent continues to disclose a topical skin treatment and method of treating various infections by applying said topical formulation comprising chelators, antibacterial agents, buffers and carriers. The formulation can be applied to surface burns in order to reduce or prevent bacterial infections. Though not explicitly disclosed, the components would work synergistically together to improve the bacterial resistance of the overall formulation.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-



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0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

/MICAHA-PAUL YOUNG/  
Examiner, Art Unit 1618